Retrospective Review of Procedural Parameters and Outcomes of Percutaneous Vertebroplasty in 673 Patients

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Summary

Percutaneous vertebroplasty (PVP) is a minimally invasive procedure to treat back pain secondary to osteoporotic vertebral compression fractures (VCF). This study aims to review our techniques and outcomes in patients with VCF.

Outcomes of all patients who underwent PVP at our institution from 1998 to 2014 were retrospectively collected from medical records and follow-up telephone interviews. 1174 PVP procedures for VCF in 673 patients were identified to have complete follow-up data. Patients with inadequate data were excluded from the analysis. Procedural aspects such as unipedicular or bipedicular access, vertebral region treated, amount of cement injected into vertebrae, number of levels treated at a single session, refracture rates and location, presence of a necrotic cavity, and pain outcomes were examined.

Excellent rates of improvement of back pain for both single level and multilevel PVP were achieved in 92% of patients. Unipedicular or bipedicular approach, cement volume, vertebral region treated, cement extravasation, and presence of a necrotic cavity did not affect pain outcomes or refracture rates. Fractures that did develop after PVP were often adjacent and occurred earlier than distant level fractures. Lumbar vertebrae required more cement than thoracic vertebrae.

PVP provides excellent rates of pain relief in both single and multilevel procedures. The procedural aspects evaluated did not affect pain outcome or refracture rates. Adjacent refractures tended to occur sooner than distant ones.

Introduction

There are an estimated 700,000 new osteoporotic vertebral compression fractures (VCF) that occur in the United States annually [1]. VCF causes severe back pain, height loss, and spinal deformity. In addition, patients may suffer impaired mobility and compromised quality of life secondary to agonizing pain [2,3]. Pain from VCF is often abrupt and intense, and may last from three to six months. Some patients develop fractures after a trivial spine trauma, and are initially asymptomatic but later develop progressive pain and kyphosis over weeks to months. This is known as Kummell's disease and is thought to be a failure of the fracture healing process [4,5].

Patients with VCF are often treated initially with conservative medical management, including narcotic analgesia, braces, immobilization, and physical therapy. However, such a regimen in the elderly may lead to deconditioning, adverse drug reactions, and functional decline [3]. Percutaneous vertebroplasty (PVP) with polymethylmethacrylate (PMMA) was initially introduced as a stabilization procedure for vertebral hemangiomas in 1987, then later successfully utilized for symptomatic osteoporotic VCF [6,7].

Good outcomes from PVP have also been demonstrated in patients with Kummell's disease, also known as avascular necrosis of the vertebral body [5]. In PVP, the vertebral body is accessed through the pedicle via a cannula and cement is injected, providing strength and sup-

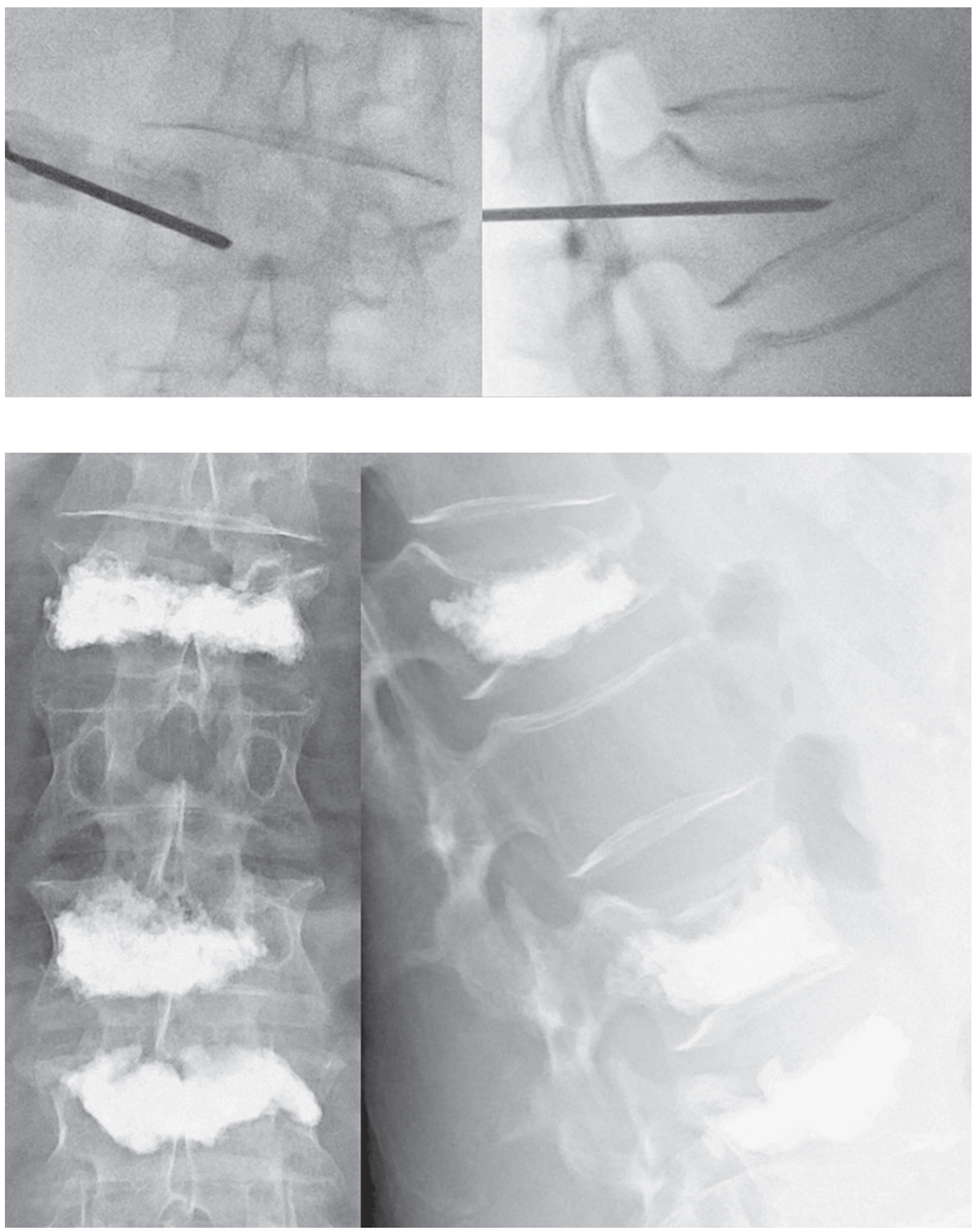

Figure 1 Multilevel PVP at L1, L3, and L4. An 85 year old man underwent successful PVP for an L1 VCF, then developed recurrent lower back pain 6 weeks later and was found to have a refracture at L3 and L4. A) Frontal view of needle placement at L1 vertebral level prior to cement injection. B) Lateral view of L1 needle placement in same patient. Frontal (C) and lateral (D) views of lumbar spine following treatment of L3 and L4 level VCF. Note the uniform density of cement in L4 indicating filling of a necrotic cavity without trabeculation.

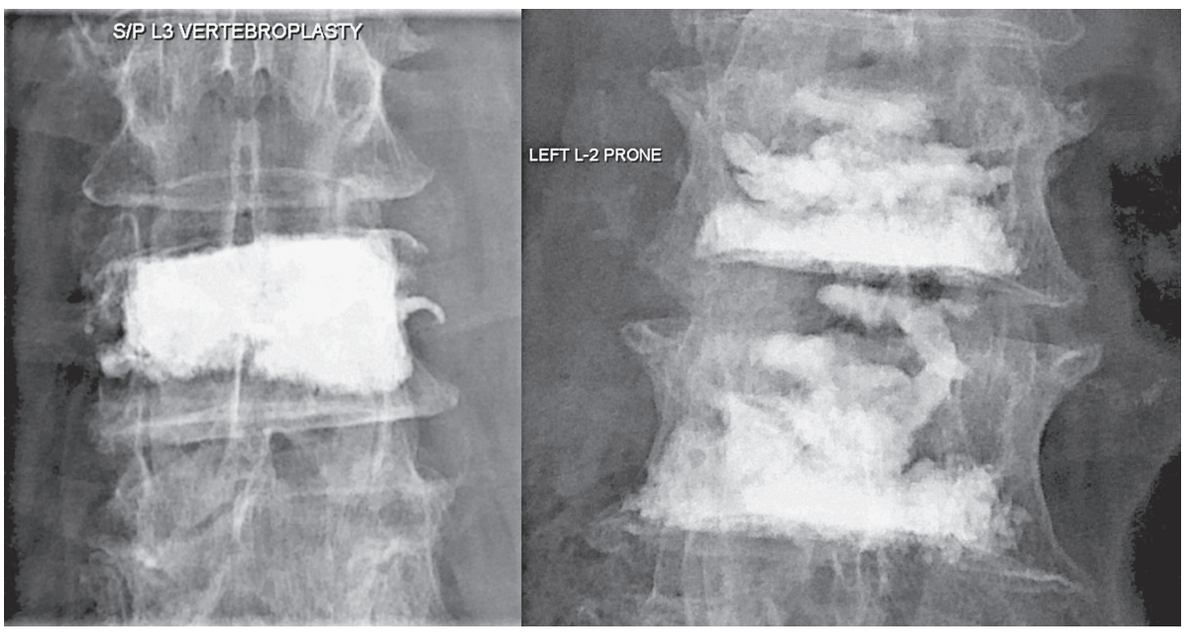

Figure 2 Cement extravasation at L3. A) Frontal view of cement extravasation in the perivertebral vein on the right. B) Frontal view of a separate patient with an L2 and L3 multilevel PVP with cement extravasation in the intervertebral disc space.

port to the vertebral body. Retrospective and prospective studies of PVP have consistently demonstrated rapid and considerable improvement in pain following treatment, with positive outcomes ranging from 80% to 90% for osteoporotic VCF [3,8-11]. Clinical complication rates for the procedure are low, ranging from 1-3% [8,12]. A similar procedure called kyphoplasty introduces balloons in the vertebral body to create cavities for deposition of PMMA [13]. In 2009, two clinical trials created controversy after failing to demonstrate the effectiveness of PVP over a sham procedure. These studies were followed by the VERTOS II trial and the FREE trial, which demonstrated the efficacy of PVP and kyphoplasty over conservative management [14-17].

Previous smaller studies have examined specific technical factors of the PVP procedure and their relation to clinical outcome. Factors such as unipedicular versus bipedicular approach, cement volume injected, adjacent post procedure vertebral fracture, and single vertebral level versus multilevel treatments have been analyzed [10,18-21]. This single center retrospective study analyzed these technical procedural variables and post procedural events in 673 patients with complete follow-up data.

Materials and Methods

Selection criteria

Institutional review board approval was granted for this study. PVP was offered to patients with radiological and clinical evidence of symptomatic acute to subacute compression fractures of the thoracolumbar spine that had corresponding point tenderness at the level of the fractured vertebrae to be treated. Sacroplasty procedures were excluded from our analysis. Patients were not offered PVP if their pain was resolving, if they responded significantly to medical pain management, or had back pain which did not correlate to the fractured spinal level or was not related to the VCF. In addition, if patients had systemic infections, significant disc herniations, significant spinal stenosis with cord compression, or unstable retropulsed vertebral fragments, PVP was not offered. Most patients were treated initially by their primary care physicians or spine surgeons with medical management, which included non-steroidal anti-inflammatory drugs such as ibuprofen or naproxen, narcotics, Tylenol, back brace, physical therapy, and rest. Patients with prolonged symptoms lasting more than four

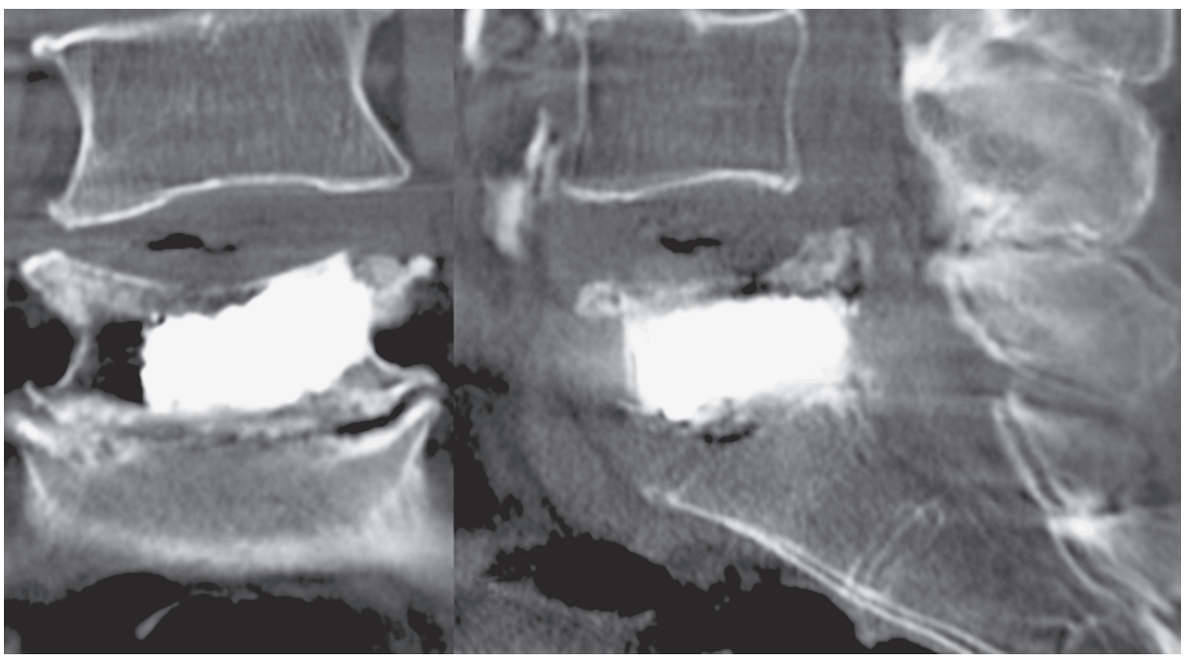

Figure 3 DynaCT rotational 3D image of L5 PVP. Coronal (A) and sagittal (B) reconstruction views of DynaCT. Note the location of cement cast in the necrotic cavity following burst fracture of L5. Lucency in the left side of the vertebral body indicates a residual cavity which is not filled with cement. No significant cement extravasation can be seen.

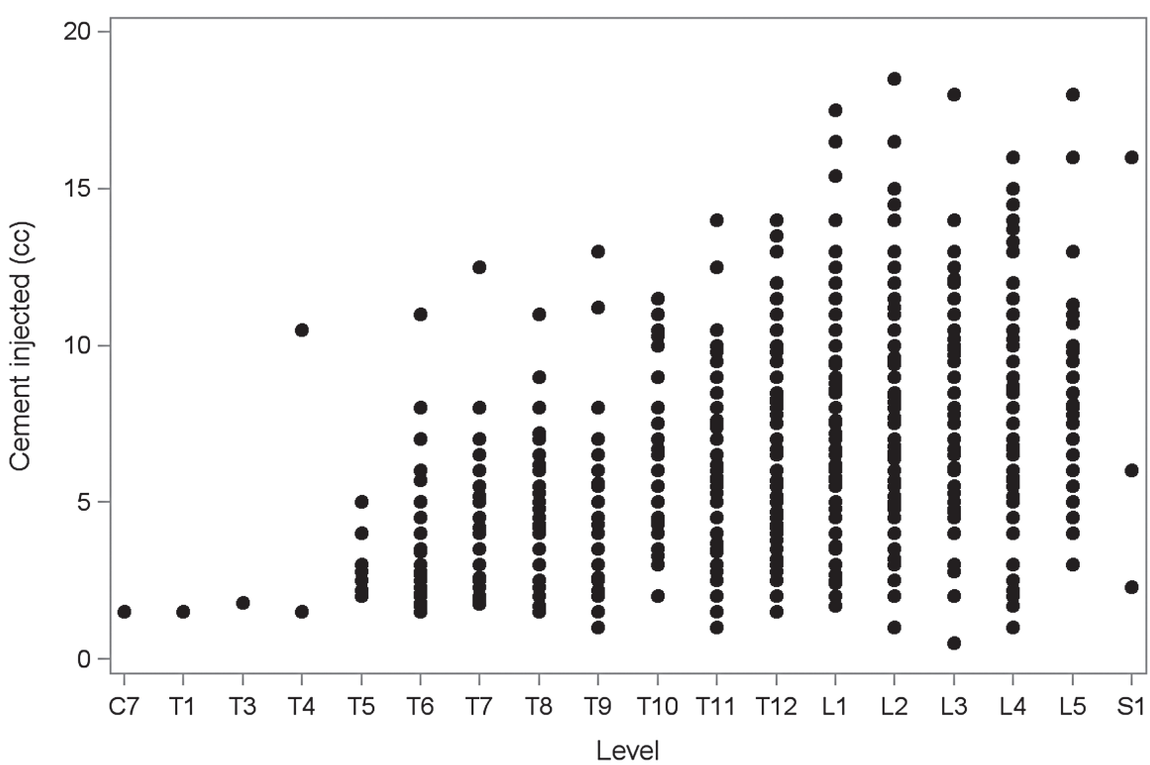

Figure 4 Distribution of cement used by vertebral level in 1174 procedures.

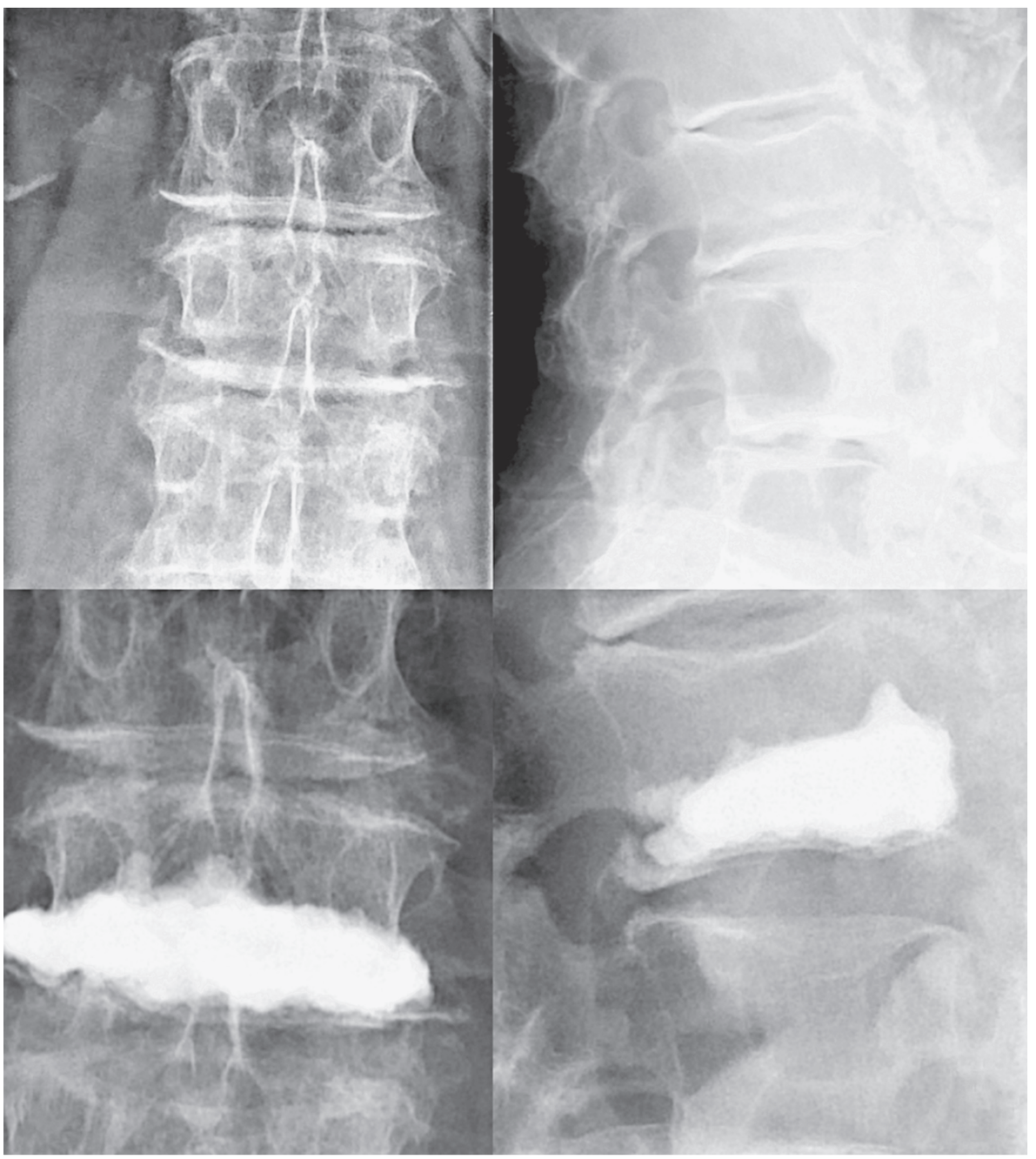

Figure 5 L3 PVP in Kummell's disease. A) Frontal view demonstrates a necrotic cavity at the inferior endplate of L3 which is more clearly seen on lateral (B) view. Complete cement placement in the necrotic cavity after PVP in frontal (C) and lateral (D) views.

weeks were treated if MR imaging continued to demonstrate edema, signifying an unhealed fracture. In cases of acute fracture, patients were treated sooner if there were no retropulsed fragments.

Patient population

There were 1373 vertebral levels treated in 860 patients treated between September 1998 and June 2014. Follow-up data were available

for 1174 PVP procedures in 673 patients who were included in our analysis. The remaining patients were excluded because of incomplete follow-up data. These 1174 procedures included treatments of a single vertebral level PVP, multilevel PVP, and refractures after an initial treatment. Of the 673 patients, 378 (56.2%) patients underwent a single level PVP, whereas 295 (43.8%) patients underwent a PVP for more than one level, including return visits for refractures. Of the total number of procedures, 570 (84.7%) patients underwent only one procedure. Of these 570 patients, 378 (66.3%) underwent a single level procedure and 192 (33.7%) underwent a multilevel procedure. Of the number of levels treated per procedure, 549 (67.11%) had a single level treatment, 192 (23.47%) had two levels, 66 (8.07%) had three levels, and 11 (1.34%) were for a four-level PVP. Average age of patients was 76.64 years (S=10.2; range= 36-101); 76.1% were female, and 23.9% were male.

Methods

Vertebroplasty procedure

All PVP procedures were performed by interventional neuroradiologists with expertise in spine interventions.

A preprocedural consultation was performed at a vertebroplasty clinic with an endocrinologist, a spine surgeon, and an interventional neuroradiologist. This consultation included extensive history-taking, a neurological examination, and evaluation of radiological images. To assess whether fractures were acute or subacute, MRI images were obtained on all patients who could obtain an MRI prior to evaluation. If a patient was not able to undergo an MRI, due to the presence of a device such as a pacemaker, a bone scan and/or CT scan was obtained. The MR imaging criteria positive for acute compression fracture include low signal intensity of bone marrow within the vertebral body on T1-weighted images and high signal intensity on T2-weighted and STIR images. Positive nuclear imaging criteria for bone scan include abnormal foci of increased radiotracer distributed within the affected vertebral segment. Potential risks of vertebroplasty were explained to the patients during consultation. These risks included bleeding, infection, nerve root compression, more vertebral fractures, paralysis, and pulmonary embolization. Informed consent was obtained prior to all PVP.

Procedures were performed under neuroleptic analgesia. Siemens Artis zee (Siemens Medical Solutions USA, Inc., Malvern, PA, USA) biplane fluoroscopy was used in all cases. After placing the patient in a prone position, the fracture levels were confirmed. Local anesthetic, 1% lidocaine, was injected into the skin and deep soft tissues near the target pedicle with a 20 gauge needle. An 18 G spinal needle was placed to determine the entry point and trajectory for the trocar needle. A 13 gauge Jamshidi Oseto-Site Bone biopsy trocar needle (Cook Inc., Bloomington, IN, USA) was advanced under fluoroscopic guidance via a transpedicular approach into the vertebral body. Biplane fluoroscopy was used to guide the appropriate trajectory and not interrupt the medial cortex of the pedicle. The needle was advanced into the anterior third of the vertebral body in an attempt to reach the midline (Figure 1A,B).

For earlier cases, orthopedic PMMA preparations and sterile barium were used. Once prepackaged preparations became available, Concord™ bone cement packets were used which consisted of a sterile powder and a sterile liquid (Algea therapies, Aububon, PA, USA). For multilevel procedures, the packet consisted of 40g of powder and 16.4g of liquid. This powdered mixture of 71.3% PMMA, 28% sterile barium sulfate, and 0.7% benzoyl peroxide was combined with powdered 500 mg vancomycin and vigorously shaken together for one to two minutes in a container. This preparation was then mixed under suction conditions in a SmartMix™ vacuum mixing bowel (Depuy Inc., Warsaw, IN, USA) with the liquid solution of 99.0% methylmethacrylate, 1.0%N,N-dimethyl-p-toluifine, and 100 ppm of hydroquinone to produce a cement dough. This dough was then drawn up in 12ml standard luer-lock syringes and capped. These syringes were immediately submerged in an ice bath of sterile sodium chloride to slow polymerization, as detailed previously by Chavali et al. [22]. These syringes were frequently rotated throughout the procedure to keep the cement evenly cooled. The cement-filled syringes were removed from this ice bath and cement was injected into 1 cc syringes for use during the procedure. From these 1 cc syringes, approximately 0.05-0.2 cc of cement was injected at a time under biplane fluoroscopic observation until complete filling

Table 1 **Procedural outcomes by vertebral region treated.**

		C7-T8	T9-T12	L1-S1	P-value
A. Vertebral region treated		176 (15%)	396 (33.7%)	603 (51.32%)	< 0.001
B. Cement volume injected.		4.0 (1.9)	6.3 (2.5)	7.3 (2.9)	<0.001
C. Pain relief outcome	**Complete**	44 (65.7%)	80 (60.2%)	143 (63.8%)	0.43
	Partial	15 (22.4%)	44 (33.1%)	65 (29.0%)	
	None	8 (11.9%)	9 (6.8%)	16 (7.1%)	
D. Refracture rates		9 (14.1%)	17 (12.2%)	36 (15.3%)	0.71

Top row lists vertebral regions analyzed and P value. N (%) = Number (percent) of patients with complete data for row A, C, and D. Row B is the mean amount of cement injected into the vertebrae (standard deviation). A. Vertebral regions treated in a total of 1175 PVP procedures, including refractures and multilevel treatments. B. Amount of cement used by vertebral region in 447 patients undergoing a single level procedure for VCF, at first encounter. C. Pain outcomes by vertebral region treated in 424 patients with complete data who underwent single level procedures, at first encounter. D. Refracture rates per vertebral region treated in 445 patients with complete data.

of a necrotic cavity was achieved or the operator deemed it sufficient. Repeated road-mapping was used throughout the procedure to determine the location of newly injected cement. Injections were momentarily stopped if venous, disk space, or epidural extravasation occurred to allow for the cement to harden (Figure 2). Injections were then restarted after approximately one to two minutes of delay. If inadequate deposition of cement into the contralateral half of the vertebral body occurred, a second needle was placed into the contralateral pedicle using the technique described and additional cement was injected. Multiple level VCF were treated one level at a time (Figure 1C,D). A DynaCT rotational 3D image was obtained after the procedure to evaluate the location of cement cast and potential extravasation (Figure 3).

Procedural details were documented immediately after the procedure, including the spinal levels treated, the number of pedicles accessed, the amount of cement injected, cement extravasation, and the presence of a necrotic cavity. Patients were instructed to remain supine for one hour post procedure then allowed to ambulate. If undergoing the procedure as an outpatient, patients were then discharged after two more hours of monitoring. Inpatients were allowed to ambulate after one hour lying supine.

Outcome measures

Follow-up telephone interviews were conducted by interventional neuroradiology nurse practitioners or registered nurses approximately two to four days after the procedure. Patients' pain relief was assessed and categorized as "complete pain relief, partial pain relief, or none". Patients were asked about changes in pain medication usage, and any new back pain or neurological symptoms that occurred. If patients reported partial or no pain relief, they were interviewed again after one week. If patients reported new back pain or worsening back pain after one week, they were evaluated for a new fracture using a MRI or a CT scan and/ or bone scan. If telephone interviews could not be obtained, pain outcomes were assessed via medical records by reviewing the next physician encounter that occurred after procedure. Inpatients were evaluated post procedure by the interventional neuroradiology staff.

Statistical analyses

Correlation analyses between procedure details and outcomes were conducted in patients with single-level procedures separately to avoid replicate counting of outcomes for patients with multiple levels treated. Comparisons between patients with single and multilevel procedures were limited to the first encounter to prevent patient clustering (non-independence) due to repeat visits and treatment of refractures. We used chi-square tests and independent samples t-tests (for two groups) or analysis of variance (for more than two groups) to assess statistical differences. All analyses were conducted using Statistical Analysis System (version 9.3) and p-values of 0.05 were used to determine statistical significance.

To prevent any clustering error in analyzing the relationship between the technical parameters of the procedure with the primary outcome of pain relief, single level treatments were initially analyzed separately from multilevel

Table 2 **Days to refracture by location.**

Days to refracture						
Refracture location	**Number of refractures (%)**	**Minimum**	**Lower Quartile**	**Median***	**Upper Quartile**	**Maximum**
Distant	23 (24%)	6.0	26.0	92.0	248.0	1800.0
Adjacent	73 (76%)	1.0	21.0	44.0	83.0	547.0
Overall	96 (100%)	1.0	23.0	47.5	100.0	1800.0

** Difference in log (days) between distal and proximal fractures is statistically significant, p=0.01.*
Days to refracture by location reported among 670 patients with complete follow-up data undergoing single or multilevel procedures at first encounter: 101(15.1%) refractures were reported, 5 were missing location data, leaving an overall of 96 refractures.

treatments. These two groups were then compared to each other. In addition, treatments for refractures were excluded in some analyses of procedural parameters to obtain a more accurate assessment of the outcomes related to a first encounter PVP, such as amount of cement injected.

Results

Of the total vertebral levels treated in 1174 procedures with complete data, 176 (15%) were from C7-T8, 396 (33.7%) were from T9-T12, and 603 (51.3%) were from L1-S1 vertebral levels. There were only four patients who underwent PVP above T5 vertebral level. In our series, PVP were performed more frequently at the lumbar region; 51.3% of procedures were performed from L1 to S1 level (Table 1A). The overall average total amount of cement injected per level treated was 6.7 cc (S=2.9 cc). The amount of cement injected by vertebral level in all 1174 procedures is shown in Figure 4. The average amount of cement injected differed per vertebral region treated, with significantly more cement being used in the lumbar vertebrae. As seen in Table 1B, 4.0cc of cement was used (s=1.9 cc) for C7-T1, 6.3 cc (s=2.5 cc) for T9-T12, and 7.3 cc (s=2.9 cc) for L1-S1 in single level procedures, at first encounter.

Of the 639 patients who underwent an initial single or multilevel procedure, 92% reported benefit to their back pain from PVP: 403 (63%) reported complete pain relief, 188 (29%) reported partial pain relief, and 48 (7%) reported no change in pain from PVP. When examining the 424 patients with complete follow-up data who underwent an initial single level treatment, 92.3% of patients reported benefit to their back pain following PVP: 267 (63%) reported complete pain relief, 124 (29.3%) partial pain relief, and 33 (7.8%) reported no pain relief following the procedure.

Pain outcomes were examined based on vertebral region treated in 424 patients with complete follow-up data (Table 1C). PVP at C7-T8 achieved complete pain relief in 44 (65.7%) patients, partial pain relief in 15 (22.4%), and no pain relief in eight (11.9%) patients. T9-T12 achieved complete pain relief in 80 (60.2%) patients, partial pain relief in 44 (33.1%), and no pain relief in nine (6.8%) patients. Lumbosacral procedure from L1-S1 achieved complete pain relief in 143 (63.8%) patients, partial pain relief in 65 (29%), and no pain relief in 16 (7.1%) patients. There was no statistically significant difference in pain outcomes when comparing regions of the cervical, thoracic, and lumbar spine (P=0.43).

Comparing patients with single or multilevel treatment at first encounter, no significant difference was found in those who underwent a single level PVP versus a multilevel PVP in terms of pain outcome, age, gender, presence of a necrotic cavity, cement extravasation, or refracture rates. However, the use of a bipedicular approach was significantly more frequent in patients undergoing a multilevel treatment: 183 (81.0%) patients who underwent a multilevel treatment required a bipedicular approach versus 306 (68.6%) of single level PVP (P<0.001). Of 215 patients who underwent a multilevel procedure at first encounter, 136 (63.3%) patients reported complete pain relief, 64 (29.8%) reported partial pain relief, and 15 (7.0%) reported no change in pain. There was no significant difference in terms of pain outcomes comparing single vs. multilevel procedures (P= 0.93).

Pain relief was compared to the amount of cement used for 424 patients with single level procedures. The mean amount of cement used

in patients reporting complete pain relief was 6.7 (S=2.9); in patients reporting partial pain relief it was 6.2 (S= 2.9), and no pain relief was 6.1 (S= 2.8). There was no correlation between the amount of cement injected and pain outcomes (p=0.23).

Of the total 1174 procedures with complete follow-up data, only 410 (35%) required only a unipedicular approach. The presence of a necrotic cavity, or Kummell's disease, was found in 376 (32%) procedures (Figure 5), and fluoroscopic evidence of cement extravasation occurred in 258 (22.2%) procedures.

In examining refractures after a PVP, only patients presenting as a first encounter single or multilevel PVP were included in our analysis, 15.1% of 670 patients with complete follow-up data developed refractures after PVP: 76% of these patients were fractures in adjacent vertebral levels and 24% were distant fractures (Figure 1C,D). As seen in Table 2, the median number of days to an adjacent refracture after PVP was 44 (interquartile range= 21-83), compared to distant fractures which occurred at a median of 92 days (interquartile range= 26-248). This difference was statistically significant (P=0.01).

The mean amount of cement used in patients who developed a refracture after a single level PVP at first encounter was 6.3 cc (S= 3.4 cc), versus a mean of 6.5 cc (S= 2.8 cc) in patients who did not did not develop a refracture. There was no significant relationship between the amount of cement used and refracture rates (P=0.54). Unipedicular versus bipedicular approach, presence of a necrotic cavity, and extravasation of cement were not associated with refracture. As seen in Table 1D, there was no significant relationship between the vertebral regions treated and refracture rates.

For single level PVP at first encounter no significant difference was found in the amount of cement used in the presence or absence of a necrotic cavity seen in fluoroscopy. The amount of cement used in 173 vertebrae demonstrating a necrotic cavity was 6.6 cc (S=2.9 cc), compared to 6.4 cc (S=2.9 cc) in 273 vertebrae without a cavity (P=0.16).

The relationship between pain outcome and procedural parameters in 525 procedures in patients who underwent single level treatments was examined. The presence of a necrotic cavity, unipedicular vs. bipedicular approach, gender, or cement extravasation were not significantly associated with pain outcome.

Discussion

The primary clinical objective of percutaneous vertebroplasty is pain relief from a vertebral compression fracture. Our study demonstrated excellent rates of improvement in pain at 92% following the procedure, which is in line with previous studies [3,8,9-11]. The mechanism underlying this pain relief is currently not confirmed, but may be related to improved strength and stiffness of the fractured vertebrae following cement injection, preventing fracture site motion affecting intraosseous or periosteal nerves [23]. Other researchers have postulated a possible thermal or chemical reaction affecting nerve endings in affected tissue [3].

Percutaneous vertebroplasty is generally a safe procedure. Two cases of small, asymptomatic, pulmonary embolisms from cement were found in our patients. There were no documented clinical complications such as radiculopathy, paralysis, or death from PVP, which corresponds to the very low rates reported from other studies [3,8,11]. Extravasation of cement material out of the vertebral body, whether through the epidural or paravertebral venous complexes, or perivertebral spaces via fracture lines or disrupted cortex, is a common observation during PVP (Figure 2). Several large case series have demonstrated rates in a quarter to a third of PVP cases [8,20,21]. Our series found that 22.2% of procedures demonstrated fluoroscopic extravasation during the procedure. Leakage of cement is mostly asymptomatic, but rarely may lead to more serious complications such as nerve root or spinal cord compression, pulmonary embolus, or death. Layton found that 25% of patients undergoing PVP had fluoroscopically visualized cement leakage outside the vertebral body. Most were asymptomatic, with only 0.45% developing clinical symptoms from this leakage such as radiculopathy and pulmonary embolus [3,8]. Their group proposed that small amounts of leakage alone should not be considered a complication of the procedure, but rather a stopping point for injection of cement when recognized. Their overall complication rate was 1.8%, and the most frequent complication encountered was rib fracture from lying prone on the fluoroscopy table [8]. In our practice, injection of cement was stopped when extravasation was recognized in a vein or extracorporeal space, then restarted again after a delay of one to two minutes to allow it to harden in the proximal vein. This allowed the cement to stay within the vertebral body or necrotic cav-

ity with further injections. A DynaCT rotational 3D image was obtained following PVP in most patients to localize cement cast and confirm if cement extravasation had occurred that was undetected on fluoroscopy (Figure 3).

Al-Ali et al. found that overall 18% of their patients underwent a second PVP within a year after an initial procedure to repair a new VCF; 12% of their patients had suffered a new adjacent VCF. They suggest that these rates are similar to the occurrence of secondary fractures in untreated VCF, suggesting a natural progression of osteoporosis [19]. Some researchers have found that those patients who developed adjacent fractures were more likely to have had leakage of cement into the adjacent disc space, possibly from diminished cushioning ability of the disc space, while others have not [20,24]. Our previous report by Uppin et al. demonstrated that patients were at an increased risk of new onset adjacent level fractures following PVP, and adjacent VCF occurred sooner than non-adjacent level fractures. It was hypothesized that the augmented stiffness of a vertebral body treated with cement may contribute to developing new adjacent VCF. This finding was redemonstrated by Trout et al. in 2006 [25,26]. Similar to those findings, our study demonstrated that 16.6% of patients developed refractures after PVP. Of these refractures, 72.2% of these were adjacent, and they occurred significantly sooner than distant refractures. We found no significant relationship between refractures and cement extravasation. Interestingly, there was no relationship between the amount of cement used and refractures. It has been proposed that biomechanical changes following treatment of a vertebral body with cement, such as vertebral loading and shape, may compromise adjacent levels. Whether these adjacent levels would have progressed to fractures due to the natural evolution of the underlying disease or clustering due to their location in the thoracolumbar spine without an initial PVP is unclear [25,26].

There has been concern that asymmetric lateral distribution of cement in the vertebral body from a unipedicular approach may lead to suboptimal biomechanics and risk of further collapse in the nonaugmented side [27]. However, some clinical and cadaveric studies have not demonstrated this concern [20,21,28]. In our series, only one needle was positioned initially on all patients undergoing PVP. If cement distribution was deemed to have insufficient central placement in the vertebral body, the contralateral pedicle was engaged and cement was injected in an attempt to achieve adequate central distribution: 69.5% of procedures required a bilateral pedicular approach. There was no significant association between pain relief or refractures and a unilateral versus a bilateral approach in our series.

Pain outcomes following PVP were independent of other procedural details, including vertebral region treated in the thoracolumbar spine, if treatment was for a single level versus multilevel fracture, for an initial fracture or a refracture after an initial PVP, or the volume of cement injected into the vertebral body. Similar pain outcomes were achieved in patients with either one level VCF or multiple levels undergoing PVP.

The presence or absence of a necrotic cavity found during fluoroscopy did not statistically affect pain outcomes in our series. This cavity may be a sign of Kummell's disease, a non-healing fracture thought to be secondary to the development of an avascular zone or ununited fracture within the vertebral body (Figure 5). Clinically, patients with Kummell's disease suffer an initial asymptomatic minor back trauma, and then weeks to months later develop progressive back pain and kyphosis. Pseudoarthrosis and air-filled fracture clefts are characteristic radiologic findings of Kummell's disease [4,5]. The presence of this cavity in our series was not associated with refractures. Surprisingly, the amount of cement used in vertebrae with a necrotic cavity was the same as in those without a cavity.

There has been debate on the optimal amount of cement required in a PVP. Some studies have presented that only 2 cc of cement is required to restore stress distribution to fractured vertebrae, but up to a minimum of 3.5 cc may be needed to restore stress stiffness, depending on the level in the thoracolumbar spine [23,29]. In addition, it is argued that biomechanical alterations from excessively high volumes of cement injected into the vertebral body may potentially compromise adjacent vertebrae. In our series, volume of cement was not correlated with pain relief or refracture rate, which was demonstrated in prior studies [18,20,22].

Our study had one possible limitation. Patient follow-ups were performed by telephone by interventional neuroradiology trained nurse practitioners or registered nurses. There may be potential unintentional bias in a patient's reporting of or nurse's collection of pain outcomes. In cases when direct patient follow-up could not be

obtained, pain outcome was determined by examining medical records documenting patient's back pain from the next physician encounter, whether from an inpatient hospitalist, an outpatient primary care physician visit, or specialist.

Conclusion

Our case series demonstrated excellent pain outcomes following vertebroplasty for VCF. Procedural parameters such as volume of cement injected, unipedicular approach versus bipedicular approach, cement extravasation, or presence of a necrotic cavity did not affect pain outcome or refractures. Treatment of multilevel fractures, or refractures after an initial treatment, can achieve the same level of success as a single level fracture. Multilevel fractures often required a bipedicular approach to achieve adequate core cement placement. Refractures after PVP were often adjacent, and these refractures occurred sooner compared to distant refractures.

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